

Remarks

Prior to this amendment, claims 2-5, 25, 27-33, 35, 36, and 80-98 were pending in this application, of which claims 27-33, 35, 36, and 82-94 have been withdrawn from consideration. Claims 2-5, 80, and 95-97 are amended herein. Claim 98 is canceled. Of the withdrawn claims, claims 33, 36, and 89-94 are amended to parallel the scope of the examined claims.

Support for the amendment of claims 2-5, 33, 36, 80, 89, 90, 92, 93, and 96 can be found in the specification at least at page 67, lines 3-4 and at page 22, lines 21-23.

Applicants believe that no new matter has been added by these amendments. Applicants reserve the right to pursue any removed subject matter in a related application. After entry of this amendment, **claims 2-5, 25, 27-33, 35, 36, and 80-97 are pending** (of which claims 27-33, 35, 36, and 82-94 continue to be withdrawn). Reconsideration of the pending claims is respectfully requested.

Withdrawn Claims

Applicants acknowledge that claims 90-94, which were added in the Amendment and Response to Non-Final Action submitted on April 7, 2009, are withdrawn from consideration for being directed to non-elected subject matter. Applicants expressly request that the withdrawn method claims be rejoined and the claims examined, at the latest upon the allowance of any of the product claims. It is believed that this is in accordance with the current Patent and Trademark Office Guidelines for Restriction Requirements in TC1600.

Withdrawal of Rejections

Applicants thank Examiner Archie for withdrawing the rejection of claims 2-4 under 35 U.S.C. §102(b), the rejection of claim 4 under 35 U.S.C. §112, first paragraph (written description), and the rejection of claims 2-4 under 35 U.S.C. §112, second paragraph. Applicants also thank Examiner Archie for withdrawing the objection to the numbering of the claims.

Claim Rejections Maintained*Claim Rejections Under 35 U.S.C. §112 (written description)*

Claims 2, 3, 5, 95-96, and 98 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the invention at the time the application was filed. Applicants traverse this rejection.

The claims are currently amended to be directed to:

- (i) residues 23-312 of SEQ ID NO: 11;
 - (ii) an amino acid sequence at least 98% identical to residues 23-312 of SEQ ID NO: 11;
- or
- (iii) an immunogenic fragment comprising at least fifteen consecutive amino acids of residues 23-312 of SEQ ID NO: 11, that specifically binds to an antibody that specifically binds residues 23-312 of SEQ ID NO: 11,
- wherein administration of the polypeptide to a subject produces an immune response to *P. ariasi*.

As established in *Ex parte Parks*, “adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed” *Ex parte Parks*, 30 USPQ2d 1234, 1236-37 (B.P.A.I. 1993) (emphasis added). Moreover, the MPEP at §2163 states that “[w]hat is conventional or well known to one of skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g. *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient”).”

In the current instance, Applicants had possession of the polypeptide sequence set forth in

residues 23-312 of SEQ ID NO: 11. The claimed genus is therefore defined by residues 23-312 of SEQ ID NO: 11 and one of skill in the art would recognize that Applicant was in possession of a structural feature shared by each of the members of the claimed genus at the time the application was filed. Thus, residues 23-312 of SEQ ID NO: 11 is a representative species of the genus.

The specification also clearly describes polypeptide variants having 98% or 99% sequence identity (see page 22, lines 21-23). In addition, conservative amino acid substitutions (see specification at page 10, line 26 through page 11, line 29) were well known at the time the application was filed and provide additional guidance with regard to envisioning variants of residues 23-312 of SEQ ID NO: 11. Furthermore variant polypeptide sequences would have been routinely made in the art at the time the application was filed, for example with the aid of a computer. Thus, one of skill in the art would have been able to envision all of the polypeptide sequences within the claimed genus.

In addition, it was well known to those of skill in the art at the time the application was filed how to identify immunogenic epitopes of known sequences. For example, MHC binding peptide databases, such as the ProPred database (<http://www.imtech.res.in/raghava/propred>), were available at the time the application was filed (Singh and Raghava, *Bioinformatics*, 17(12):1236-1237, 2001). ProPred is a graphical web tool which can predict which regions of a known antigenic protein sequence binds class II MHC molecules and this database could have been used by one of skill in the art at the time the application was filed to identify immunogenic epitopes in the genus of polypeptides defined by residues 23-312 of SEQ ID NO: 11. Thus, Applicants submit that a person of ordinary skill would have envisioned the claimed genus of immunogenic polypeptides, given the knowledge and level of skill in the art at the time the application was filed, the teachings of the specification, and the provision of residues 23-312 of SEQ ID NO: 11.

In light of the above arguments and amendments, Applicants submit that claims 2, 3, 5, 95-96, and 98 are sufficiently described by the specification and request that the rejection of these claims under 35 U.S.C. §112, first paragraph, be withdrawn. In light of the above

discussion and amendments, Applicants respectfully request that this rejection be withdrawn.

New Grounds for Objection

Claims 27, 33, 35-36, and 82-88 are objected to as allegedly unclear because the status identifiers recite “withdrawn and previously presented.” Claims 27, 33, 35-36, and 82-88 are amended to correct the status identifiers to recite that these claims are “withdrawn” or “withdrawn and currently amended,” as appropriate. Applicants believe that the current status identifiers comply with 37 CFR 1.121 and respectfully request that this objection be withdrawn.

Claim 80 is objected to for being of improper dependent form for failing to further limit the subject matter of a previous claim. As current claim 80 is amended to recite that the “polypeptide comprises residues 23-312 of SEQ ID NO: 11” and claim 4, from which it depends, is amended to recite that the “polypeptide comprises an amino acid sequence at least 99% identical to residues 23-312 of SEQ ID NO: 11,” Applicants respectfully submit that claim 80, as amended, further limits the subject matter of claim 4. In view of the amendment of claim 80, Applicants respectfully request that the objection of claim 80 be withdrawn.

Claims 2-3 and 5 and dependent claims 4, 80, and 95-97 are objected to for allegedly being unclear because they recite the phrase “set forth as.” Solely to advance prosecution in this case, claims 2-5, 80, and 95-97 are amended to remove “set forth as.” In light of the above amendments, Applicants respectfully request that the objection of claims 2-5, 80, and 95-97 be withdrawn.

New Grounds for Rejection

Claims 4 and 80 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because claim 4 is directed to “a polypeptide comprising the amino acid sequence set forth as SEQ ID NO: 11” whereas dependent claim 80 recites “wherein the polypeptide consists of an amino acid sequence set forth as SEQ ID NO: 11.” As discussed above, claims 4 and 80 are amended so that claim 80 further limits the subject matter of claim 4. In light of the

amendments of claims of claims 4 and 80, Applicants respectfully request that the rejection of claims 4 and 80 be withdrawn.

Conclusion

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the number listed below.

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